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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,156	08/27/2004	Bryan E. GARNER	5233.012.NPUS01	5155

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EXAMINER
SHAW, AMANDA MARIE

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/711,156	GARNER, BRYAN E.	
	Examiner	Art Unit	
	Amanda M. Shaw	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 16-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/27/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2007 has been entered.

Claims 1-10 and 16-17 are currently pending. Claims 1 and 4 have been amended. Therefore Claims 1-10 and 16-17 will be addressed herein.

Withdrawn Rejections

2. The rejection made under 35 USC 112 1st paragraph (new matter) over the phrase "obtaining a liquid suspension sample" in section 2 of the Office Action of November 1, 2006 is withdrawn in view of the Applicants arguments. The rejections made under 35 USC 112 1st paragraph (new matter) over the phrases "preparing a series of progressively dilute samples" and "utilizing an estimation model" in section 2 of the Office Action of November 1, 2006 is withdrawn in view of amendments made to the claims.

The rejections made under 35 USC 112 2nd paragraph over the phrases "relative quantity", "progressively dilute" and "estimation model" in section 3 of the Office Action

of November 1, 2006 are withdrawn in view of the Applicants amendments to the claims. The rejections made under 35 USC 112 2nd paragraph over the phrases "substantial entirety" and "recovery media" in section 3 of the Office Action of November 1, 2006 is withdrawn in view of Applicants arguments.

The rejections made under 35 USC 102(b) over claims 1-2, 4, 7-8, 10, and 16-17 as being anticipated by Begum in section 4 of the previous Office Action of November 1, 2006 are withdrawn in view of Applicants amendments.

The rejection made under 35 USC 103(a) over claim 3 as being obvious over Begum in view of Thomas in section 5 of the previous Office Action of November 1, 2006 are withdrawn in view of Applicants amendments.

The rejections made under 35 USC 103(a) over claims 5-6 as being obvious over Begum in view of Pahuski in section 6 of the previous Office Action of November 1, 2006 are withdrawn in view of Applicants amendments.

The rejection made under 35 USC 103(a) over claim 9 as being obvious over Begum in view of Lucchini in section 7 of the previous Office Action of November 1, 2006 are withdrawn in view of Applicants amendments.

The rejection made under 35 USC 103(a) over claim 11 as being obvious over Begum in view of DesRosier in section 8 of the previous Office Action of November 1, 2006 are withdrawn in view of Applicants amendments.

Information Disclosure Statement

3. The information disclosure statement filed May 15, 2007 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered. In the instant case the Applicants submitted an IDS form but did not cite any references on the form.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

<u>This rejection is newly presented:</u>

5. Claims 1-8, 10, and 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over Mantynen (International Journal of Food Microbiology 1997) in view of Yamamoto (US Patent 5670315 Issued 9-1997).

Regarding Claim 1 Mantynen et al teach a method comprising: obtaining a liquid suspension sample comprising different microorganisms removed from a microbial treated food product and which includes a substantial entirety of a previously applied and viable microorganism of interest from a known quantity of the microbial treated food product; preparing in a manner corresponding to a most probable number model a series of dilutions, conducting a PCR analysis on the dilutions; and using the most probable number model to determine the concentration of the viable microorganism of interest present based on the results of the PCR. Specifically Mantynen teach a method which utilizes a most probable number PCR assay for detection and enumeration of enterotoxin C producing Staphylococcus aureus from fresh cheese (Abstract). Mantynen teaches that S. aureus was grown and a known amount was added to 1 liter of milk. The milk was then used to make fresh cheese (Page 136, column 2 to Page 137, column 1). For enumeration of S. aureus from cheese, ten fold dilution series from all the samples were prepared. The original and diluted samples were subjected to PCR. As a result the minimum concentration which was amplified was determined. The second lowest dilutions that gave the entC1 amplification product were used to prepare a three fold serial dilution series with three replicates per dilution. These were subjected to PCR and from the amplification results the numbers of positive and negative tubes were scored. The MPN scores were transformed into density

estimates using a computer program followed by multiplication with dilution factors (Page 138, column 2 to Page 139, column 1, Figure 2 and Table 1).

Mantynen does not teach a method further comprising a step of incubating the series of progressively dilute test samples for a predetermined period of time under conditions conducive to growth of the microorganism of interest.

However Yamamoto teaches that in the most probable number method a sample is diluted, a predetermined portion of each sample dilution is inoculated into a culture medium in a test tube and incubated for a sufficient period thereafter occurrence of cell growth is observed for each tube, and the statistic treatment of the result give the most probable cell number of the specimen (Column 1 lines 45-55).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Mantynen by performing a step of incubating the series of progressively dilute test samples for a predetermined period of time under conditions conducive to growth of the microorganism of interest. as suggested by Racioppi. While the prior art of Racioppi teaches that an incubation step is not required when the most probable number method is combined with PCR (Column 2, lines 25-47), one would be motivated to perform this step anyway in instances where it is desirable to only detect viable microorganisms because PCR detects both viable and non viable microorganisms however by adding a incubation step this minimizes the number of non viable microorganisms present in the sample.

Regarding Claim 2, Mantynen teaches that two PCR primers that are specific for the detection of the entC1 gene of S. aureus were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification (Page 138, Column 2). Therefore Mantynen teach a method wherein at least one oligonucleotide hybridizes with a nucleic acid sequence that is indicative of a species of the specific kind of microorganism.

Regarding Claim 3 Mantynen teaches that in addition to the MPN-PCR method the colony forming units of S. aureus in the cheese samples were enumerated using ten replicate plated of Baird-Parker medium. The identity of the colonies was confirmed with PCR using entC1 specific primers. Then the plate counting method was used to determine the cfu of each sample. This number was then compared to the cfu obtained by the MPN-PCR method (Page 137 Column 1 and Table 1). Thus Mantynen teaches a method wherein the sample is cultured on a plate of media.

Regarding Claim 4 Mantynen teach a method wherein the samples were tested in triplicate (Fig 2). Therefore Mantynen teach a method wherein the samples were prepared by dividing the original sample into multiple portions and detecting the presence of the organism of interest in each portion.

Regarding Claim 5 Mantynen teach a method wherein the sample is diluted 1:3 and then the samples were tested in triplicate (Fig 2). Therefore Mantynen teach a method wherein the samples were prepared by diluting the sample and dividing the diluted sample into multiple portions and detecting the presence of the organism of interest in each portion.

Regarding Claim 6 Mantynen teach a method wherein the sample is diluted 1:3 and then the samples were tested in triplicate (Fig 2). Therefore Mantynen teach a method wherein the samples were prepared by diluting the sample with a liquid to produce a fluid mixture and then dividing the mixture into multiple portions and detecting the presence of the organism of interest in each portion.

Regarding Claim 7 Mantynen teaches that two PCR primers that are specific for the detection of the entC1 gene of S. aureus were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification (Page 138, Column 2). Therefore Mantynen teach a method wherein the PCR analysis includes detecting the presence or absence of a product of hybridization since if the primers cannot hybridize to the target a PCR product is not formed.

Regarding Claim 8, Mantynen teaches that two PCR primers that are specific for the detection of the entC1 gene of S. aureus were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification (Page 138, Column 2). Mantynen further teaches that they were able to detect a 801 bp fragment of the entC1 gene using primers 1 and 2 and they were also able to detect a 631 bp fragment of the entC1 gene using primers 3 and 4 (Fig 1).

Regarding Claim 10, Mantynen teaches a method wherein the detecting of the presence or absence of a product includes performing electrophoresis. Specifically they detected the presence of a 631 bp band and a 801 bp band (Fig 1).

Regarding Claim 16, Mantynen teaches a method wherein the microorganism of interest is a harmful or undesirable organism. Mantynen teaches the detection of the S aureus, which produces heat stable enterotoxins, which can cause food poisoning (Page 135 Column 1). Therefore S. aureus is being interpreted as a harmful organism.

Regarding Claim 17, Mantynen teaches a method wherein the harmful or undesirable microorganism of interest is S. aureus (Abstract).

This rejection is newly presented:

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mantynen (International Journal of Food Microbiology 1997) in view of Yamamoto (US Patent 5670315 Issued 9-1997) as applied to claims 1 and 8 above, and in further view of Lucchini (Federation of European Microbiological Societies 1998).

The teachings of Mantynen and Yammamoto are presented above.

Regarding Claim 9 the combined references do not teach a method wherein one PCR primer hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism.

However Lucchini et al teach a method wherein multiplex PCR was performed using four oligonucleotide primers. Two genus specific primers named LARNA5 and LARNA6 were used. These primers were specific to a conserved region of 248 bp within the 16S rRNA gene of lactobacilli. Two species-specific primers named APF3

and APF4 were also used. These primers were specific to L. gasseri (Page 274, column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Mantynen and Yamamoto so as to have used one PCR primer which hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism for the added benefit of being able to distinguish between different species when more than one species is suspected of being present in the sample to be tested.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7, and 9-16 of Application No 10711155. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-11 and 16-17 are generic to all that is recited in claims 1, 7, and 9-16 of Application No. 10711155. That is, claims 1-11 and 16-17 of Application No 10711155 fall entirely within the scope of claims 1, 7, and 9-16 or, in other words, claims 1, 7, and 9-16 are anticipated by claims 1-11 and 16-17 of Application No. 10711155. Specifically, both sets of claims encompass methods for quantifying the presence of a microorganism in a sample of material using at least one oligonucleotide. The present claims allow the detection of any type of microorganism in any type of sample by culturing the sample and using an oligonucleotide to detect the microorganism. The claims of the Application No. 10/711155 are specific for the detection of Lactobacillus, L. acidophilus, and Lactobacillus LA-51 in samples of animal feed that are transported from an animal feedlot to a laboratory for culturing and using

an oligonucleotide to detect the microorganism. Accordingly, the detection of these specific microorganisms in animal feed is encompassed by the presently claimed methods.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

8. In the response filed April 2, 2007, Applicants stated that pending client documentation a terminal disclaimer will be filed to overcome the non-statutory double patenting rejection. As of the date that this Office Action was created the Office has not yet received the terminal disclaimer. Accordingly, the rejection is maintained.

Conclusion

9. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

BJ FORMAN, PH.D.
PRIMARY EXAMINER